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Impact of Preoperative Antibiotic Use in Preventing Complications of Cochlear Implantation Surgery

Running head: Do preoperative antibiotics prevent infectious complications in CI patients?

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Impact of Preoperative Antibiotic Use in Preventing Complications of Cochlear Implantation Surgery

Running head: Do preoperative antibiotics prevent infectious complications in CI patients?

Abstract

Objective: There is no clear evidence or guidelines on the use of preoperative antibiotics in cochlear implant surgery. The purpose of this study is to examine the impact of preoperative antibiotic prophylaxis on the occurrence of postoperative complications.

Materials and Methods: Data of 491 patients undergoing cochlear implantation were included in a non-randomized retrospective comparative cohort study conducted according to STROBE guidelines. The patients' demographic data, cochlear implant and surgical details, use of preoperative antibiotics and occurrence of postoperative complications were analysed. The primary endpoint was the occurrence of postoperative infection requiring revision surgery. Associations between variables were assessed using a binary logistic regression model.

Results: There were 317 patients (64.56%) who did not receive preoperative antibiotic prophylaxis and 174 (35.44%) patients who received preoperative antibiotic prophylaxis with ceftriaxone. The overall rate of complications requiring surgical treatment was 2.85%. Younger patient age was identified as a positive predictive factor for administering preoperative antibiotic prophylaxis ($p<0.001$, OR 1.05 CI 95% 1.0124-1.0826). Younger surgeons were less inclined to give antibiotics, and no difference in complication rate was observed between the two groups. The model showed no correlation between sex, age, manufacturer, surgeon and postoperative complications regardless of the type of complication ($p=0.45$).

Conclusion: There is insufficient evidence to inform decision making regarding preoperative intravenous ceftriaxone use for prevention of infection after cochlear implantation surgery, with data failing to show that administration of preoperative antibiotics leads to a decrease in complication rate. Considering a very low overall complication rate, with few complications related to infection, routine use of preoperative antibiotic prophylaxis should be analysed further.

Keywords: preoperative antibiotics; ceftriaxone; cochlear implant; complication; infection; revision; explantation

Introduction

Cochlear implantation is a surgical means for providing auditory rehabilitation in patients with severe-profound sensorineural hearing loss. Cochlear implants are electronic devices that directly stimulate the cochlear nerve. Increased availability and advancing technology are permitting more patients to undergo cochlear implantation (Naples & Ruckenstein, 2020).

Despite significant advances in surgical care, postoperative infection remains an important complication. There are several types of infection occurring after cochlear implantation which can endanger not only hearing results, but also the patient's life (Barker & Pringle, 2008). The most common are surgical site infection, otitis media and meningitis. The infection occurs as a result of interaction between the device, patient's tissue and microorganisms (Sayed-Hassan et al., 2019).

A cochlear implant is a foreign body and due to lack of microcirculation, is prone to biofilm formation. A biofilm represents a complex bacterial community and is strongly protected from host defence mechanisms. Biofilm formation may even require implant removal in complicated cases

unresponsive to antibiotic treatment and may result in severe complications such as cochlear ossification (Naples & Ruckenstein, 2020).

In order to prevent infectious complications, many authors suggest the use of preoperative antibiotic prophylaxis. The chosen antibiotic must be effective against most common pathogens (Vijendren et al., 2020). The most commonly found pathogens in patients with infections related to cochlear implantation are Staphylococcus aureus and Pseudomonas aeruginosa species. Infection with Pseudomonas spp are associated with a particularly high likelihood of requiring device explantation due to the high resistance to antibiotic treatment and pseudocapsule formation (Kabelka et al., 2010; Vijendren et al., 2020). Wound infections are usually caused by S. aureus as a result of skin colonization (Cunningham et al., 2004; Hopfenspirger et al., 2007). Meningitis is commonly caused by Streptococcus pneumoniae and Haemophilus influenzae (Reefhuis et al., 2003). Despite the low overall complication rate after cochlear implantation surgery (1-13%), postoperative infection requiring implant removal is associated with significant patient morbidity, and often requires prolonged hospitalization (Vijendren et al., 2019). For these reasons, prophylactic antibiotic treatment is generally considered cost-effective.

Antibiotic prophylaxis, if chosen correctly, should be efficient against common pathogens. However, liberal use of antibiotics leads to bacterial resistance which is a significant issue in clinical medicine, while adverse effects of antibiotics, such as drug toxicity, may also complicate their use (Sayed-Hassan et al., 2019).

There is no clear evidence or guidelines on preoperative antibiotic use in cochlear implant surgery. The purpose of this study is to examine the impact of perioperative antibiotic prophylaxis on the occurrence of postoperative complications.

Materials and Methods

Data of 497 patients undergoing cochlear implantation for severe-profound sensorineural hearing loss were included in a non-randomized retrospective comparative cohort study conducted according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (von Elm et al., 2014). The study was approved by the University Hospital Centre Bioethical Board adhering to the Helsinki Declaration Revision of 1989. Inclusion criteria were met if the patients underwent cochlear implantation surgery between January 1, 1996 and January 1, 2019 in our tertiary referral centre, the procedures were performed by the same otologic team, and data on preoperative antibiotic use and postoperative complications were available during a minimal one-year postoperative follow-up interval. Exclusion criteria were insufficient data on preoperative antibiotic treatment or patients with incomplete postsurgical follow-up.

Indications for cochlear implantation in adults were bilateral postlingual deafness, bilateral sensorineural hearing loss with a Pure Tone Average (PTA) threshold of 70 dB HL (500, 1000, 2000 and 4000 Hz average) and speech discrimination score <50% at 65 dB with hearing aids. In paediatric patients, indications were bilateral sensorineural hearing loss >80dB HL confirmed by behavioral hearing tests.

Patient demographic data, cochlear implant manufacturer information, primary surgeon, use of preoperative antibiotics and occurrence of postsurgical complications were entered into a comprehensive database.

Informed consent was obtained from all patients and/or their legal guardians. The primary endpoint was occurrence of postoperative complications, whether requiring explantation of the device or

revision surgery resulting in preservation of the implanted device. Statistical analysis was performed using SPSS software (Version 22.0 © 2013. IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp), using standard descriptive statistics and frequency tabulation as indicated. Associations between variables were assessed using a binary logistic regression model with odds ratios (OR) and confidence intervals. All tests of statistical significance were performed using a two-sided 5% type I error rate.

Results

Demographic data

The total number of patients who met the inclusion criteria is 491. Six patients were excluded due to insufficient data on preoperative antibiotic use or incomplete postsurgical follow-up. There were 262 male and 229 female patients. Most patients were children under the age of 18 (86%), 422 in total. The adult population, 69 patients, accounted for 14% of cases. The average age of patients was 13.7 years (11 months - 83 years).

Administration of antibiotics

There were 317 patients (64.56%) who did not receive preoperative antibiotic prophylaxis and 174 (35.44%) patients who received preoperative antibiotic prophylaxis. Paediatric patients who received preoperative prophylaxis were all given ceftriaxone intravenously 50 mg/kg 60 minutes prior to the skin incision, with a maximum dose of 1,000 mg. Adult patients received 1 gram of ceftriaxone intravenously 60 minutes prior to the skin incision (Kimberlin et al., 2018.)

Complications

The overall rate of complications that required surgical treatment was 2.85%. In total, there were 6 revision surgeries without device explantation due to skin flap breakdown and fixation suture fistula (3), and hematoma (3) (Figure 1). In addition, there were 8 explantations without reimplantation because of allergic reactions to silicon (1) and titanium (1). One patient complained of continuous severe tinnitus. There was one case of meningitis and one case of soft tissue breakdown with biofilm formation (Figure 2). There were three patients requiring explantation due to severe headache.

Four patients developed transient facial palsy which resolved spontaneously. Two additional patients who developed postoperative hematoma were successfully treated with needle aspiration and compression without the need for revision surgery.

Five patients who received preoperative antibiotic prophylaxis developed complications resulting in revision surgery, in comparison to nine patients requiring revision surgery in the group that did not receive preoperative prophylaxis. The number of explanted devices was 8 yielding an overall explantation rate of 1.63%.

The data were analysed using a binary logistic regression model. Age was identified as a positive predictive factor for administering preoperative antibiotic prophylaxis, with younger children having a higher probability of receiving antibiotics ($p<0.001$, OR 1.05 CI 95% 1.0124-1.0826). Younger surgeons were less inclined to give antibiotics, and no difference in complication rate was observed between the two groups.

The model showed no correlation between sex, age, manufacturer, the administration of preoperative antibiotics, surgeon and postoperative complications regardless of the type of complication ($p=0.45$).

An additional analysis was performed of patients who were treated with oral antibiotic therapy due to trauma-related hematoma formation over the cochlear implant (20 patients, 4.1%) and concern about developing early implant infection due to acute otitis media episodes during the first postoperative year (24 patients, 4.9%). None of the patients in this additional analysis had confirmed infectious episodes requiring intravenous or surgical treatment. The overall results remained unchanged after this additional analysis. There was no statistical significance between the two groups.

Discussion

The use of preoperative antibiotic prophylaxis in cochlear implant surgery is a practice adopted by most surgeons (Barker & Pringle, 2008). The significance of infections related to cochlear implantation was brought under scrutiny in 2002, when the United States Food and Drug Administration received reports of bacterial meningitis in patients with cochlear implants (Basavaraj et al., 2004). However, no clear guidelines currently exist supporting the use of antibiotic prophylaxis. A 2004 Cochrane systematic review concluded that there is no benefit from prophylactic antibiotics in clean or clean-contaminated ear surgery, although this study did not address cochlear implantation specifically (Verschuur et al., 2004). Two additional systematic reviews were published in 2016 and 2019 that addressed this topic (Anne et al., 2016; Vijendren et al., 2019). Neither arrived at a definite conclusion due to the lack of high-quality evidence. No randomised controlled trials have been performed to date. The major argument in favour of antibiotic prophylaxis is the severity of postoperative infection which is often difficult to treat and may require device explantation, or can lead to life-threatening complications such as meningitis (Wei et al., 2008). However, complications after cochlear implantation surgery are uncommon and

some complications are not related to microbial colonization. The likelihood of avoiding device explantation also depends on the microorganism present, while complications such as skin flap breakdown and suture fistula can be avoided with refinements in surgical technique (Nash et al., 2019). Infections caused by H. influenzae and S. pneumoniae can be reduced with vaccination which is highly recommended in paediatric patients undergoing cochlear implantation (Reefhuis et al., 2003).

Our study found that the overall rate of complications after cochlear implantation was low (2.85 %) which is consistent with findings in other similar studies(Hirsch et al., 2007; Kabelka et al., 2010; Vijendren et al., 2019). However, in only 40% of cases when a severe infection occurs after surgery can the device be saved and avoiding explantation (Vijendren et al., 2020). This is due to the difficulty in treating surgical site infections despite the use of intravenous antibiotics and wound irrigation (Vijendren et al., 2019, Van Osch et al., 2020). The explantation rate in our study was 1.63% and the causes were silicon and titanium allergy, tinnitus, meningitis, soft tissue breakdown, infection with biofilm formation, and headache. Only 2 of the 8 explantations were performed due to infection. The remaining 6 cases of explantation could neither be prevented nor treated with antimicrobial therapy.

There is no current consensus on the choice of preoperative antibiotic treatment. Antibiotic administration is dependent on institutional policies, assumed pathogens and personal preferences. Typical prophylactic antibiotics include cephazolin, ceftriaxone, cefuroxime, clarithromycin, co-amoxiclav and clindamycin/vancomycin in cases of penicillin hypersensitivity. Our study included ceftriaxone as a prophylactic regimen in all patients. There are numerous different guidelines on the time of the antibiotic administration. The American Society of Health-System Pharmacists (ASHP) suggests the administration of antibiotic prophylaxis 0-60 minutes prior to incision in order

to achieve optimal tissue concentration. Hirsch et al and Almosnino et al reported administration 30 minutes before the skin incision while Yalamanchi reported the average time of administration 17.5 minutes before surgery (Almosnino et al., 2018; Hirsch et al., 2007; Yalamanchi et al., 2020). In our study, both paediatric and adult patients received ceftriaxone intravenously 60 minutes prior to the skin incision.

Our results demonstrate that age was a positive predictive factor for administering preoperative antibiotic prophylaxis. 90.28% of patients who received prophylaxis were children. Some authors have found that children have a higher complication rate compared to adults, which may explain why surgeons are more inclined to recommend antibiotic prophylaxis for paediatric patients (Sayed-Hassan et al., 2019). Other studies have found the complication rate to be similar in adult and paediatric patients (Vijendren et al., 2020). There was no correlation between age and the infection rate in our cohort.

Our results revealed no correlation between the surgeon and postoperative complications. Senior surgeons were more likely to prescribe antibiotic prophylaxis. Perhaps due to advancements in surgical techniques and experience passed on by senior surgeons, younger surgeons were less inclined to prescribe antibiotic prophylaxis.

The limitations of our study are the potential for selection bias in our cohort and the lack of randomization. However, selection bias may not be a significant issue, since all surgeries were performed under identical surgical indications, in the same OR, and by the same surgical team as the younger surgeons acquired their operative technique directly from the mentor surgeons. The overall number of complications in this study was small, limiting the ability to generate definitive conclusions. Further studies of preoperative antibiotic use in cochlear implantation with larger sample sizes are warranted.

Conclusion

There is insufficient evidence to inform decision making about preoperative intravenous ceftriaxone use for prevention of infection after cochlear implantation. This study did not demonstrate that administration of preoperative antibiotics leads to a decrease in complication rate. Considering there is a very low overall complication rate after cochlear implantation, with few complications directly related to infection, this study did not provide evidence to warrant the routine use of preoperative antibiotic prophylaxis.

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Conflict of Interest: The auhors have no conflicts of interest.

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Figures and Legends

Figure 1. A patient with recurrent spontaneous hematoma and pain in the cochlear implant region undergoing revision surgery. Preoperatively, an X-ray of the right temporal region showed a diastasis between the processor and the internal magnet of the implant measuring up to 20 mm.

Figure 2. A patient with soft tissue breakdown. The overlying periostal and skin flap necrosis led to implant exposure. Revision surgery was performed, using a local transpositional skin flap to cover the implant with excellent functional and aesthetic results.